

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Comparing The Efficacy Of Metacognitive Group Therapy And Cognitive - Behavioral Group Therapy On Reducing Of The Symptoms And Metacognitive Factors Of Social Anxiety Disorder In Students: Double Blind Randomized Clinical Trial.

#### Protocol summary

##### Study aim

Comparing The Efficacy Of Metacognitive Group Therapy And Cognitive-Behavioral Group Therapy On Reducing Of The Symptoms And Metacognitive Factors Of Social Anxiety Disorder In Students.

##### Design

This clinical trial has two intervention groups and one control group, double blind and randomized ones.

##### Settings and conduct

After a diagnostic interview by a psychiatrist, patients who are diagnosed with social anxiety disorder are assigned randomly into intervention1, intervention2 and control groups. Evaluation is also performed three months after the intervention. The place of interview and intervention is the Department of Psychiatry and Clinical Psychology of Zanjan University of Medical Sciences

##### Participants/Inclusion and exclusion criteria

Inclusion criteria : 1. Tendency to participate in research; 2. A score of between 21 and 40 (mild to moderate social anxiety) in the SPIN; 3. 18 years and older; 4. Residence in Zanjan during research; 5. Being a student. Exclusion criteria: 1. At the same time receive psychological treatment; 2. Absence of more than two continuous sessions in therapeutic sessions; 3. Lack of participation in one of the three stages of evaluation; 4. History of psychosis, alcohol related disorders, bipolar disorder and personality disorders; 5. At the same time taking psychiatric medications.

##### Intervention groups

The first group will receive cognitive behavioral group therapy and the second group will receive metacognitive group therapy. The third group will not take any intervention on them.

##### Main outcome variables

Symptoms of social anxiety disorder; social phobia; social interaction; fear of negative evaluation; cognitive-

attentional syndrome; negative meta-cognitive beliefs about risk and uncontrolledness; positive beliefs about worry; cognitive confidence; cognitive self-awareness; need for thought control

#### General information

##### Reason for update

##### Acronym

CBT & MCT

##### IRCT registration information

IRCT registration number: **IRCT20190518043626N1**

Registration date: **2019-05-23, 1398/03/02**

Registration timing: **prospective**

Last update: **2019-05-28, 1398/03/07**

Update count: **1**

##### Registration date

2019-05-23, 1398/03/02

##### Registrant information

##### Name

Fatemeh Rezaei Khodadadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 24 3353 3400

##### Email address

fatma.rezaei72@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-06-01, 1398/03/11

**Expected recruitment end date**

2019-07-17, 1398/04/26

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparing The Efficacy Of Metacognitive Group Therapy And Cognitive - Behavioral Group Therapy On Reducing Of The Symptoms And Metacognitive Factors Of Social Anxiety Disorder In Students: Double Blind Randomized Clinical Trial.

**Public title**

Comparing The Efficacy Of Metacognitive Group Therapy And Cognitive - Behavioral Group Therapy On Reducing Of The Symptoms And Metacognitive Factors Of Social Anxiety Disorder In Students.

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Tendency to participate in research. A score of between 21 and 40 (mild to moderate social anxiety) in SPIN. Age of 18 years and older. Residence in Zanjan city during research. Being a student.

**Exclusion criteria:**

At the same time receive psychological treatment. Absence of more than two continuous sessions in therapeutic sessions. Lack of participation in one of the three stages of evaluation. History of psychosis, alcohol related disorders, bipolar disorder and personality disorders. At the same time taking psychiatric medications. Score 15 to 25 in BDI-II.

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Data analyser

**Sample size**

Target sample size: **48**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

After diagnosis by a specialist, patients are assigned to treatment groups 1, 2, and control group, regardless of their specific characteristics, by software, so that all participants have the odds of being in groups.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

After selecting a sample, none of the sample individuals will know about the randomization process and allocation process to the groups. The data analyst is selected

outside of the study, and all data will be encoded.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of zanjan University of Medical Sciences

**Street address**

Crossroads of Saadi, Gate of the Citadel, Shahid Beheshti Hospital

**City**

Zanjan

**Province**

Zanjan

**Postal code**

45156-13191

**Approval date**

2019-05-15, 1398/02/25

**Ethics committee reference number**

IR.ZUMS.REC.1398.036

**Health conditions studied****1****Description of health condition studied**

social anxiety disorder

**ICD-10 code**

F40.1

**ICD-10 code description**

Social phobias

**Primary outcomes****1****Description**

Symptoms of Social Anxiety Disorder.

**Timepoint**

Pre-test, post-test and follow-up (three months after the post-test).

**Method of measurement**

Conver social phobia Questionnaire (SPIN) and social interaction anxiety scale (SIAS).

**2****Description**

social phobia.

**Timepoint**

Pre-test, post-test and follow-up (three months after the post-test).

**Method of measurement**

Conver social phobia Questionnaire (SPIN).

**3**

**Description**

Social interaction.

**Timepoint**

Pre-test, post-test and follow-up (three months after the post-test).

**Method of measurement**

social interaction anxiety scale (SIAS).

**4**

**Description**

Fear of negative evaluation.

**Timepoint**

Pre-test, post-test and follow-up (three months after the post-test).

**Method of measurement**

Fear of negative evaluation of short form questionnaire (FNES-B).

**5**

**Description**

Cognitive-attentional syndrome.

**Timepoint**

Pre-test, post-test and follow-up (three months after the post-test).

**Method of measurement**

CAS-1.

**6**

**Description**

Negative metacognitive beliefs about risk and uncontrollability.

**Timepoint**

Pre-test, post-test and follow-up (three months after the post-test).

**Method of measurement**

MCQ-30.

**7**

**Description**

Positive metacognitive beliefs about worries.

**Timepoint**

Pre-test, post-test and follow-up (three months after the post-test).

**Method of measurement**

MCQ-30.

**8**

**Description**

Cognitive Confidence.

**Timepoint**

Pre-test, post-test and follow-up (three months after the

post-test).

**Method of measurement**

MCQ-30.

**9**

**Description**

Cognitive self-awareness.

**Timepoint**

Pre-test, post-test and follow-up (three months after the post-test).

**Method of measurement**

MCQ-30.

**10**

**Description**

Need to control thought.

**Timepoint**

Pre-test, post-test and follow-up (three months after the post-test).

**Method of measurement**

MCQ-30.

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: Cognitive-behavioral group therapy  
Based on Hoffman model.

**Category**

Behavior

**2**

**Description**

Intervention group: Metacognitive group therapy.

**Category**

Behavior

**3**

**Description**

Control group: No intervention.

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Zanjan University of Medical Sciences.

**Full name of responsible person**

saeedeh zenoozian

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Azadi Square, Zanjan University of Medical Sciences.

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
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Alireza Shoghli  
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**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Zanjan University of Medical Sciences  
**Proportion provided by this source**  
100  
**Public or private sector**  
Public  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
empty  
**Country of origin**  
**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
Zanjan University of Medical Sciences  
**Full name of responsible person**  
Saeedeh Zenoozian  
**Position**  
Assistant Professor  
**Latest degree**

Ph.D.  
**Other areas of specialty/work**  
Psychology  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

### **Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

### **Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

### **Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

### **Informed Consent Form**

Yes - There is a plan to make this available

### **Clinical Study Report**

Yes - There is a plan to make this available

### **Analytic Code**

Undecided - It is not yet known if there will be a plan to

make this available

### **Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

### **Title and more details about the data/document**

All information about the original outcome will be published with the likes of it.

### **When the data will become available and for how long**

Get started since 1400.

### **To whom data/document is available**

Researchers working in academia.

### **Under which criteria data/document could be used**

Access to the documentation is possible for other researchers. Access to the documentation is possible with the researcher.

### **From where data/document is obtainable**

Shaheed Beheshti Hospital, Zanjan, Department of Clinical Psychology, Dr. Saeedeh Zooszian. Tel: 09032180053 Zanjan Shahid Beheshti Hospital, Department of Clinical Psychology, Fatemeh Rezaei Khodadadi. Tel: 09130514827

### **What processes are involved for a request to access data/document**

The required documentation will be shared only by mentioning the reason for the request by email or telephone.

### **Comments**